UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge

DEFENDANTS' (PROPOSED) SURREPLY IN FURTHER OPPOSITION TO MEDICAL MONITORING PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

INTRODUCTION

Plaintiffs have had three years to develop a framework in support of their proposed medical monitoring classes. Now, at the eleventh hour, they present a radically revised plan under the guise of a reply brief. Plaintiffs' newest arguments are as meritless as their prior ones. First, Plaintiffs' new proposal for grouping proposed class members from different states is still incoherent and unworkable. Second, their pivot to a new medical monitoring proposal comes far too late and would prejudice Defendants. Third, the primary authorities upon which Plaintiffs rely are outliers, and Plaintiffs misstate numerous medical monitoring standards. And, finally, Plaintiffs' proposed "Lifetime Cumulative Thresholds"—upon which their entire motion for class certification is premised—remain unsupported by Plaintiffs' own experts, let alone by science. For these reasons, and those stated in Defendants' Response brief, Dkt. 2012, the Court should deny the Medical Monitoring Plaintiffs' Motion for Class Certification.

ARGUMENT

A. Plaintiffs' New State Law Groupings Do Not Cure The Fundamental Defects That Preclude Class Certification.

Plaintiffs try to salvage their unworkable medical monitoring classes by proposing—for the first time—that the Court divide the Independent Claim Class and Remedy Class according to whether states require: (1) "present physical injury"; (2) "a showing of subcellular injury"; or (3) no injury at all. (Reply in Supp. of the Medical Monitoring Pls.' Mot. for Class Cert., Dkt. 2059 ["MM Reply Br."] at 7.) In so doing, Plaintiffs have effectively conceded that their entire motion to certify medical monitoring classes was based on a false premise: that the "***one*** arguably meaningful difference" between the state laws is whether medical monitoring is an independent claim or remedy. (Mem. of Law in Supp. of the Medical Monitoring Pls.' Mot. for Class Cert., Dkt. 1750 ["MM Br."] at 7 [emphasis added].) Because Plaintiffs waited for their reply brief to

offer their new proposal, it is waived and should not be considered. *See Szaloczy v. Kone Elevators & Escalators*, No. 3:20-cv-3815, 2021 U.S. Dist. LEXIS 121998, at *12 (D.N.J. June 29, 2021) ("'New arguments in the reply brief are waived.'") (quoting *Rivers v. Nat'l Ass'n of Letter Carriers, Loc. 673*, No. 15-cv-3070, 2016 U.S. Dist. LEXIS 11679, at *5 (D.N.J. Feb. 1, 2016) (citing *Anspach v. City of Phila.*, 503 F.3d 256, 259 (3d Cir. 2007))).

Even if Plaintiffs' latest proposal had been timely, it would still fail on the merits. Most fundamentally, Plaintiffs do not explain how the essential element of subcellular injury—which "require[s] competent expert testimony," according to Plaintiffs' own cited caselaw, *Donovan v. Philip Morris USA, Inc.*, 914 N.E.2d 891, 901 (Mass. 2011)—could possibly be proven on a class-wide basis. Instead, Plaintiffs argue that they have "***alleged***" that "all members of the proposed Class have suffered cellular damage and/or genetic harm by their exposure to NDMA and/or NDEA[.]" (MM Reply Br. at 6 [emphasis added].) But Plaintiffs have the burden of showing that the essential subcellular element can be proven with common evidence, *see Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011) ("Rule 23 does not set forth a mere pleading standard. A party seeking class certification must affirmatively demonstrate his compliance with the Rule[.]"), and they have failed to do so. Rather, Plaintiffs rely upon the reports of David Madigan and Dipak Panigrahy, neither of which supports Plaintiffs' position. Specifically, the portions of Dr. Madigan's report cited by Plaintiffs purport to identify Lifetime Cumulative Exposure ("LCE") levels to NDMA and NDEA and the putative cancer risks associated with each level (*see* Madigan Rep., Dkt. 1750-2, at 8-10), whereas the portion of Dr. Panigrahy's report cited by Plaintiffs addresses the purported biological plausibility that NDEA causes cancer through genetic changes (*see* Panigrahy Rep., Dkt. 1750-3, at 163-64). Neither expert purports to identify LCE levels at which individuals supposedly experience "cellular damage and/or genetic harm" (MM Reply Br.

at 6), much less provide valid scientific support for such an opinion.

Moreover, in those states that require a showing of cellular or subcellular damage, Plaintiffs' proposed medical monitoring classes would fail for the additional reason that they would devolve into a series of mini-trials as to which class members have suffered "cellular damage and/or genetic harm" and which have not. These additional individualized inquiries would compound all of the predominance and ascertainability obstacles discussed in Defendants' opposition brief (including the determination of what monitoring each putative class member would receive absent alleged NDMA/NDEA exposure), confirming that Plaintiffs' eleventh-hour proposal is as deficient and unworkable as their original one.

B. The Court Should Reject Plaintiffs' Attempt To Request New Relief.

Plaintiffs acknowledge—as they must—that all medical procedures involve some risk. (*See* MM Reply Br. at 12-13.) But Plaintiffs argue that the risks to class members posed by their proposed medical monitoring regimen are outweighed by the potential benefits. (*Id.*) The opposite is true as to many potential class members: the proposed medical monitoring regimen would put their health at risk with no concomitant benefit. (*See* Chan Rep., Dkt. 2009-16, ¶¶ 48-55; Teitelbaum Rep., Dkt. 2009-25, 24-25.) For example, the FDA estimates that exposure to radiation from a CT scan increases the risk of death from cancer by about 1 in 2,000 patients. (*See* Chan Rep. ¶ 85.) Similarly, Dr. Kaplan identified the risk of a perforated colon (which can be fatal) during a colonoscopy at approximately 1 in 3,000 patients based on his years of experience. (Kaplan Dep., Dkt. 2024-4, 48:8-21.[1]) By contrast, according to the FDA, the ***theoretical*** excess

[1] Similarly, the United States Preventative Services Task Force estimates 5.4 perforations per 10,000 colonoscopies. *See* Final Recommendation Statement Colorectal Cancer: Screening, available at https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last accessed May 19, 2022).

risk of developing cancer from exposure to NDMA in affected VCDs taken at the highest dose every day for four years is 1 in 8,000. (*See* FDA News Release, May 2, 2019 "Laboratory analysis of valsartan products," Dkt. 2009-12.) For NDEA, FDA's *theoretical* excess risk estimate is 1 in 18,000. (*Id*.) These risks demonstrate precisely why a "physician would not recommend the medical monitoring procedure" for some class members, and why a proper assessment of the medical necessity of the proposed medical monitoring would have to evaluated on a patient-by-patient basis. *Arch v. Am. Tobacco Co*., 175 F.R.D. 469, 490 (E.D. Pa. 1997) (denying motion to certify medical monitoring class because "the appropriateness of screening procedures would vary from plaintiff to plaintiff"). Ultimately, the medical monitoring regimen that Plaintiffs have proposed would subject putative class members to greater health risks than even FDA's conservative, theoretical, estimated, worst-case exposure to Defendants' VCDs—all the more so for putative class members who did not take the highest dose and/or who took the medications for less than four years.

Faced with these arguments, Plaintiffs essentially abandon Dr. Kaplan's medical monitoring plan, suggesting that the Court can craft an entirely different remedy after a class is certified. (MM Reply Br. at 11-12.) Plaintiffs request this new relief ***for the first time*** in a reply brief to their class certification motion. As a result, Defendants in this MDL have had ***no notice*** and no opportunity to evaluate or respond to Plaintiffs' new proposal because, until now, the sole relief requested by Plaintiffs was in the form of Dr. Kaplan's medical monitoring program. That is the only requested relief at issue, and the Court should reject Plaintiffs' prejudicial attempt to ambush Defendants with a new proposal at the end of the class certification process.

Plaintiffs' new "certify now, figure out the details later" approach is not only untimely but also contrary to the law. Plaintiffs cite *Hardwick v. 3M Co*., No. 2:18-cv-1185, 2022 WL 668339,

at * 26 (S.D. Ohio Mar. 7, 2022) (applying Ohio law), for the proposition that the Court can establish a "science panel" for the development of a monitoring program post-certification. But without a sufficiently detailed explication of the injunctive relief being proposed, a court cannot make an informed (much less reasoned) judgment on whether "injunctive relief . . . is appropriate respecting the class as a whole." Fed. R. Civ. 23(b)(2). As a result, "[a]t the class certification stage, the injunctive relief must be described in reasonably particular detail such that the court can at least 'conceive of an injunction that would satisfy" Rule 65(d) (which governs injunctions), "***as well as the requirements of Rule 23(b)(2)***." *Shook v. Bd. of County Comm'rs*, 543 F.3d 597, 605-06 (10th Cir. 2008) (affirming denial of Rule 23(b)(2) class certification because "plaintiffs have eschewed any effort to give content to what it would mean to provide adequate mental health staff, adequate screening, or an adequate system for delivering medication") (emphasis added). Indeed, the Fifth Circuit recently vacated certification of a toxic exposure, medical monitoring class because the description of the requested monitoring did not specify "the range or types of medical monitoring the injunction would implement." *Prantil v. Arkema Inc.*, 986 F.3d 570, 581 (5th Cir. 2021) (district court's reasoning that medical monitoring is an "iterative process . . . through which 'a more complete understanding of the potential consequences of exposure is attained and treatment plans are put into place'" was an abuse of discretion). In short, *Hardwick*—which is currently the subject of a Rule 23(f) petition to the Sixth Circuit—is a clear outlier and should not be followed.

C. Plaintiffs' Misstate The Relevant Medical Monitoring Laws.

Plaintiffs include new legal authority in their reply, but it is only insofar as it was not cited in their previous briefing. In fact, apart from *Hardwick*, the only cases Plaintiffs cite certifying medical monitoring classes are decades old, which is not surprising given the broad recognition in

this circuit and beyond that medical monitoring claims are far too individualized for class treatment. *See Gates v. Rohm & Haas Co.*, 655 F.3d 255, 264 (3d Cir. 2011). Plaintiffs rely primarily on *In re Diet Drugs Prod. Liab. Litig.*, No. CIV.A. 98-20626, 1999 WL 673066 (E.D. Pa. Aug. 26, 1999), which has been widely criticized and rejected by courts over the last two decades. *See, e.g.*, *In re Fosamax Prod. Liab. Litig.*, 248 F.R.D. 389, 396 & n.8 (S.D.N.Y. 2008) (noting that "[l]ower courts almost unanimously have rejected class certification in pharmaceutical products liability actions, including those seeking medical monitoring for a heightened risk of future injury, because the proposed class actions failed to satisfy many of Rule 23's requirements" and that *Diet Drugs* was a rare "exception"); *Perez v. Metabolife Int'l, Inc.*, 218 F.R.D. 262, 274-75 (S.D. Fla. 2003) ("Although it certified the class action, the court in the *Diet Drugs* case noted significant manageability problems, stating that '[t]here exist individual issues which will be a challenge to the court and the parties in resolving the class claims, including individual factual issues and variance of applicable state law.' This Court believes that these manageability problems predicted and since encountered by that Pennsylvania District Court would only be magnified in this case . . ."); *In re Baycol Prod. Litig.*, 218 F.R.D. 197, 212 (D. Minn. 2003) (denying certification of a medical monitoring class, finding *Diet Drugs* unpersuasive, and noting that "Plaintiffs have not, however, sufficiently addressed how the Court would manage the class through subclasses, nor have they sufficiently established what the subclasses would be and which states would be grouped in which subclass. Plaintiffs cannot meet their burden of demonstrating that class certification is superior."); *In re Propulsid Prod. Liab. Litig.*, 208 F.R.D. 133, 146-47 (E.D. La. 2002) ("It should be noted that at the time of the *Diet Drugs* certification order, the plaintiffs had not briefed the issue of varying state law because they were proceeding under the assumption that Pennsylvania law would apply to the entire class. The district court, therefore,

ordered briefing on the issue of varying state law with the understanding that the court's certification order would be modified as required so as to create a number of subclasses based upon the variance of . . . medical monitoring law . . . [However,] [c]onditional certification of a class action involving multiple state laws without analyzing the effect of this variation on the manageability of the trial is not permitted in the Fifth Circuit."). This Court should follow the overwhelming weight of authority rejecting the outdated approach of *Diet Drugs*.

Plaintiffs also criticize Defendants for supposedly misstating the relevant medical monitoring standards, but Plaintiffs' critiques are themselves inaccurate, confirming the unworkability of trying a medical monitoring class that implicates the complicated and disparate laws of numerous states. By way of example:

- Plaintiffs argue that Arizona would recognize an independent claim for medical monitoring, relying on *Burns v. Jaquays Mining Corp*., 752 P.2d 28, 33 (Az. Ct. App. 1987), but *Burns* addressed medical monitoring as a form of damages for a nuisance claim. As recognized by the Arizona Supreme Court in *Quiroz*: "*Burns* concluded that . . . the medical costs associated with monitoring the residents' subclinical injuries was recoverable in the context of a nuisance claim. . . . The Family reads too much into *Burns*. The Family has never alleged that Reynolds created a nuisance. Perhaps more importantly, *Burns* did not address duty; it addressed damages." *Quiroz v. ALCOA Inc*., 243 Ariz. 560, 568-69 (2018).

- Relying on a twenty-year-old state trial court opinion, Plaintiffs argue Montana would recognize an independent claim for medical monitoring. *See Lamping v. Am. Home Prods., Inc*., 2000 WL 35751402, at *1-2 (Mont. Dist. Ct. Feb. 2, 2000). A recent federal court interpreting Montana law, however, found *Lamping* unpersuasive because it "is more than twenty years old, is unpublished, has not been acknowledged by other Montana courts, and only recognized medical monitoring on that case's specific facts." *In re Zantac (Ranitidine) Prod. Liab. Litig*., 546 F. Supp. 3d 1152, 1164 (S.D. Fla. 2021).

- Plaintiffs state that "[t]he New Jersey Supreme Court has held that whether an injury arises from a toxic tort 'in itself is not a distinguishing metric.'" (Pls.' Reply at 7 n.10 (citing *Sinclair v. Merck & Co*., 195 N.J. 51, 71 (2008) (Long, dissenting) ("*Ayers*, *Mauro*, and *Theer* were toxic tort cases, but that factor, in itself is not a distinguishing metric.").) This quote, however, was taken from the ***dissenting*** opinion, which rightfully acknowledged that New Jersey precedent on medical monitoring claims has been limited to the toxic tort context. The majority opinion of the court found that because plaintiffs could not prove a physical injury under the NJPLA, plaintiffs could not recover for medical monitoring

> damages, with the court also noting that "environmental tort actions" are excluded from NJPLA actions. *Compare See Ayers v. Twp. of Jackson*, 525 A.2d 287, 298 (N.J. 1987) (medical monitoring expenses may be awarded based on risk of future disease caused by exposure to pollutants).

These examples illustrate the widely divergent nature of state medical monitoring law across the country. Moreover, Plaintiffs' reply ignores the varying state laws governing the substantive causes of action (*e.g.*, negligence) underlying Plaintiffs' proposed Remedy Class. In short, Plaintiffs have failed to identify adequate support for their motion to certify unprecedented nationwide medical monitoring classes.

D. Plaintiffs Cannot Overcome The Lack Of Support For Their Proposed LCTs.

Finally, despite all their efforts to pivot and offer new proposa6ls, Plaintiffs, tellingly, are still unable to explain the basis for their proffered "Lifetime Cumulative Thresholds." As Plaintiffs tacitly acknowledge, absent defined thresholds, they cannot overcome the controlling standard set forth by the Third Circuit in *Gates*, 655 F.3d 255. (*See* MM Reply Br. at 8.) Yet, despite having every opportunity to do so, neither Plaintiffs nor their proffered experts—Dr. Madigan and Dr. Panigrahy—have ever disclosed how the purportedly "conservative" LCTs were calculated. Madigan and Panigrahy did not author supplemental reports, and their general causation reports are silent as to LCTs. Further, with regard to NDEA, both Madigan and Panigrahy have been limited with regard to the opinions they are permitted to offer. (*See Daubert* Order 1, Dkt. 1958.) Recognizing these limitations, Plaintiffs cite, for the first time, to other general causation experts—Dr. Hecht and Dr. Lagana—in support of their medical monitoring claims. But Plaintiffs never proffered either of these experts in support of their medical monitoring classes; nor do these experts address the concept of LCTs in their prior reports or testimony. As a result, Plaintiffs cannot properly rely upon Hecht or Lagana to support their proposed LCTs, or in connection with their motion to certify medical monitoring classes more generally. Moreover, Defendants' unchallenged

experts, Dr. Ballman and Dr. Chodosh, both explain in detail why Plaintiffs' LCTs are not grounded in reliable science. (*See* Ballman Rep., Dkt. 2009-24, 12, 17; Chodosh Suppl. Rep., Dkt. 2009-26, ¶ 15.) If any scientific support existed for Plaintiffs' LCTs, then Plaintiffs would have presented it to the Court. Their silence speaks volumes.

CONCLUSION

For the foregoing reasons, as well as those set forth in Defendants' Response Brief, Plaintiffs' motion for class certification should be denied.

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Respectfully submitted,

By: */s/ Clem C. Trischler*

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